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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,894	11/30/2001	Michael Hutchinson	0922/63690	4202

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12/15/2004

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,894

Applicant(s)

HUTCHINSON, MICHAEL

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-17 is/are rejected.
- 7) ☒ Claim(s) 5-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

2. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The examiner notes applicants' admission that the geometric variation/degeneration of the substantia nigra as related to Parkinson's disease is known (see p. 815 1st col., 1st ¶ and 2nd col., 2nd full ¶ of article (1) of record; and p. 897 1st col., 1st ¶ and p. 698 2nd col., 5th ¶ of article (2) of record, both incorporated by reference by applicant). The examiner also notes applicants' admission that it is common practice in MRI to use ratios to objectively quantify signals (see 1st col., 2nd ¶

on p. 817 of article (1), incorporated by reference). The examiner further considers “resultant signals differentiating between PD and PSP” to be related to the inherent geometry of the measured SNc tissue. In addition, the examiner understands that other MRI sequences or parameters that produce WMS and GMS MRI images differing from each other may equivalently be used instead of inversion-recovery pulse sequences (see ¶ [0013]).

Claim Objections

3. Claims 1, 10, 12 and 15 are objected to because of the following informalities: In claims 1, 10 and 12, it appears that “substania” should be changed to –substantia--. In claim 15, it appears that “substantial” should be changed to –substantia--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claims 1-11, 13, 14, 16 and 17, the specification does not adequately describe how a white matter suppressed (WMS) signal of SNc tissue is used to produce resultant signals indicative of PD or PSP (it appears, rather that WMS

signals of peduncular or crus cerebri regions are obtained (cp. 1st col., 3rd full ¶ on p. 698 of article (2), incorporated by reference)). Regarding claims 10 and 11, the specification does not adequately disclose how information is combined from the GMS and WMS images to produce signals indicative of PSP. Regarding claims 12-14, the specification does not adequately disclose how the MRI images are combined to differentiate between PD and PSP. Regarding claims 15-17, the specification does not adequately describe how the MRI images are combined to identify PSP.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 9, 15 and 16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gosche.

Regarding claims 1, 9, 15 and 16 Gosche discloses a method for detecting a variety of neurological disorders (including Parkinson's) by obtaining volumetric measurements indicative of atrophy due to a pathological process (col. 8 lines 39-58, col. 9 line 66 – col. 10 line 18). Gosche further discloses obtaining a plurality of images and performing segmenting/thresholding (i.e., suppressing) to classify GM, WM, CSF, etc. (e.g., col. 9 lines 33-40). Gosche further discloses using different MRI parameters (col. 11 lines 51-64). Although Gosche does not explicitly address SNc tissue, the whole brain image data (including subcortical structures) of Gosche inherently includes this region (see e.g., fig. 2-8). Alternatively, it would have been obvious at the time the invention was made to a person of ordinary skill in the art to specifically image the substantia nigra in the invention of Gosche when diagnosing a neurological disorder such as Parkinson's as is well known in the art (as per applicants' admission in article (1), p. 815 1st col., 1st ¶ and 2nd col., 2nd full ¶; and article (2) p. 697 1st col., 1st ¶ and p. 698 2nd col., 5th ¶, incorporated by reference). In addition, PD inherently involves a loss

from lateral to medial portions of the SNc (as evidenced in article (1) p. 817 2nd col. 4th full ¶ and article (2) p. 698, 2nd col., 5th ¶, incorporated by reference).

6. Claims 2-4, 10-13, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gosche.

Regarding claims 2, 3, 14 and 17, Although Gosche discloses T1 imaging, inversion recovery (IR) pulse sequences are not explicitly addressed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use inversion recovery pulse sequences because Applicant has not disclosed that such sequences provide an advantage, are used for a particular purpose, or solve a stated problem (see e.g., ¶ [0013]). One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the multispectral data set based on PD, T1, and T2 sequences of Gosche since both enable WM/GM delineation for detecting neurological atrophy indicative of Parkinson's disease.

Regarding claim 4, although Gosche does not explicitly address obtaining a ratio image, it would have been obvious at the time the invention was made to a person of ordinary skill in the art to take a ratio of the different images of Gosche to objectively quantify signals for subsequent comparison/analysis as is well known in the art (as per applicants' admission in article (1) p. 817 1st col., 2nd ¶, incorporated by reference).

Regarding claims 10-13, although Gosche does not explicitly address detecting PSP, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to detect PSP because Applicant

has not disclosed that such detection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the detection of PD as taught by Gosche because both are able to diagnose presence and severity of a neurological disorder related to PD (see e.g., Gosche col. 8 lines 51-58 and col. 9 lines 20-26).

Allowable Subject Matter


7. Claims 5-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw
Primary Examiner
Art Unit: 3737
12/7/2004